(12) UK Patent Application (19) GB (11) 2 272 770 (13) A

(43) Date of A Publication 25.05.1994

- (21) Application No 9223200.8
- (22) Date of Filing 05.11.1992
- (71) Applicant(s)

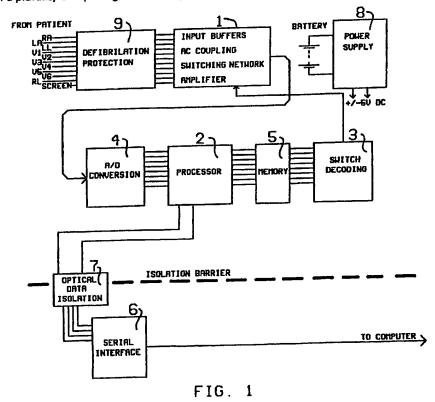
Alan John Bishop llex Innovations, Hollies Lodge, Manchester Road, ROCHDALE, Lancs, OL11 3QY, United Kingdom

- (72) Inventor(s) Alan John Bishop
- (74) Agent and/or Address for Service L J Bray & Co. Raw Holme, Midgehole Road, HEBDEN BRIDGE, West Yorkshire, HX7 7AF, United Kingdom

- (51) INT CL5 A61B 5/028
- (52) UK CL (Edition M) **G1N NECG N19B2P N30P1**
- (56) Documents Cited EP 0080821 A2 WO 86/02538 A1 GB 2264176 A WO 81/02832 A1 US 5054496 A
- Field of Search UK CL (Edition L) G1N NEAE NECG NESS INT CL5 A61B Online database: WPI

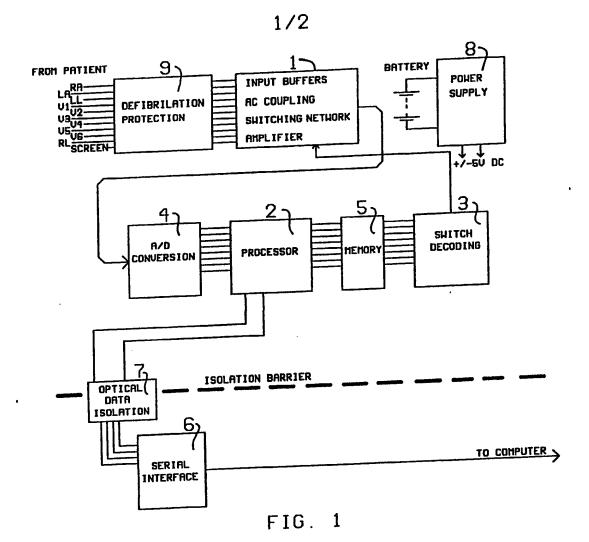
(54) Interface for electrocardiograph

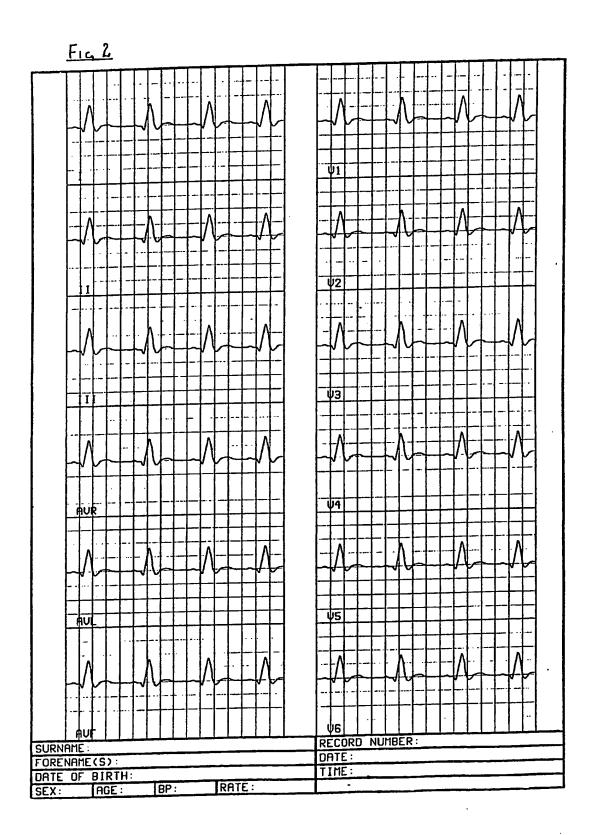
(57) An interface unit for an electrocardiograph comprises data input means (1) for connection to electrodes for attachment to a patient and data output means (6) whereby the unit can be connected to an input of a computer in order to provide two-way communication between the interface and the computer. A memory (5) capable of storing signal information from the data input means is provided along with a processor (2) which controls operation of the memory. The processor is connected to the data output means so that it can output data to the computer as requested via signals received from the computer. Preferably, switch means are provided connected to the input means and controlled by the processor so that signal information relating to a selected one of a plurality of input signals can be processed at any given time.



At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1990.





IMPROVEMENTS TO ELECTROCARDIAGRAPHS

The present invention relates to electrocardiagraphs and in particular to an interface unit for use as part of an electrocardiagraph.

In conventional electrocardiagraph equipment the electrical activity of a patient's heart is recorded and analysed. This is usually accomplished by complex dedicated electronic apparatus, which is comparatively expensive. The main reason for the expense is the incorporation into the apparatus of a display screen and printing means to enable traces of a patient's heart activity to be viewed on screen and printed out for future reference. This has the disadvantage that such dedicated apparatus is generally only available for use by hospitals and medical specialists and is normally beyond the means of general practitioners.

A primary object of the present invention is to overcome or substantially mitigate the aforementioned disadvantage.

According to a first aspect of the present invention interface unit for provided an electrocardiagraph comprising data input means for connection to electrodes for attachment to a patient, data output means whereby the unit can be connected to an input of a computer to provide two-way communication between the interface and the computer, a memory capable of storing signal information from the data input means, and a processor which controls operation of the memory and which is connected to the data output means so that it can output data to the computer as requested via signals received from the computer.

Preferably, switch means are provided connected to the input means and controlled by the processor so that signal information relating to one of a plurality of input signals can be processed at any given time.

Preferably also, the data input means comprises nine input channels for signals from nine input electrodes and one output reference electrode.

Preferably also, the processor can receive signal information from all the input channels at least once every 2 mS.

Preferably also, the memory can store at least 2000 samples of the signal information from each input channel.

Preferably also, an analogue to digital converter is provided to convert each sample of the signal information from each of the input channels into an eight bit value for storage in the memory.

Preferably also, the data output means comprises an isolation barrier to isolate the interface unit and thereby the patient electrically from the computer when the interface unit is connected thereto.

Preferably also, the data input means comprises defibrillation protection means to protect the interface unit electrically from a defibrillation voltage administered to the patient.

Preferably also, the defibrillation protection comprises at least one voltage sensitive switch.

Preferably also, the data output means comprises a serial interface to enable signal information to be transmitted to and from the computer via a serial data input port of the computer.

According to a second aspect of the present invention there is provided an electrocardiagraph comprising a computer; electrodes for attachment to a patient; and an interface unit comprising data input means connected to the electrodes, data output means connected to an input port of the computer to provide two-way communication between the interface and the computer, a memory capable of storing signal information from the data input means, and a processor which controls operation of the memory and which is connected to the data output means so that it can output data to the computer as requested via signals received from the computer.

Thus, the invention provides the means whereby a conventional computer such as a personal computer or similar can be converted into an electrocardiagraph permitting two-way communication and the means whereby information relating to the patient's cardiac activity can be stored for future analysis. This is accomplished by linking an interface unit according to the first aspect of the invention to a computer which will then operate as an electrocardiagraph when appropriate software, intended to be supplied with the interface unit, is run by the computer. However, the invention also has the advantage that the interface unit can operate alone and will store information for later down-loading into a computer for analysis.

An example of the invention will now be described with reference to the accompanying drawings, in which:-

:.

Fig. 1 is a block diagram of an interface unit according to the first aspect of the invention; and

Fig. 2 is a representation of a sample printout which can be obtained from an electrocardiagraph according to the second aspect of the invention.

The interface unit shown in Fig. 1 comprises an input means 1 capable of being attached to conventional cardiac activity electrodes for attachement to the skin of a patient and which are typically available separately and Preferably, there are nine disposable. electrodes RA, LA, LL, V1, V2, V3, V4, V5, and V6 corresponding to right arm, left arm, left leg, and six chest electrodes, and one output reference electrode RL, corresponding to the right leg electrode. These electrodes can be connected to the input means 1 in any conventional fashion such as via a 15 way D type connector.

Within the input means 1, is an input buffer wherein each of the electrode inputs is connected to a respective unity gain amplifier which responds to changes in potential with respect to the common electrode RL produced by cardiac activity of the patient. The output of each of the nine amplifiers is provided with AC coupling to remove any DC offset caused by electrode connection and amplifier voltage offsets, and also to function as a bandpass filter to incoming signals.

From the input buffer, each of the nine signals is connected to an analogue switch circuit, which is under the control of a processor 2 via a switch decoder 3. The processor controls the switch decoder 3, which in turn operates the switch circuit in the input means 1 so that each of the nine input signals is selected in turn for further processing. It is envisaged that all nine of the

signals will be processed every 2mS so that 500 samples will be taken per second. The selected signal is amplified to provide suitable voltage levels and a DC offset is supplied at this stage to make the signals compatible with an analogue to digital converter 4 to which the signal is then input.

The analogue to digital converter 4 outputs an eight bit representation of the momentary value of the selected input signal presented to it via the analogue switch. This signal status is then output directly to the processor 2 wherein it is processed and stored under processor control in a memory 5.

The memory 5 comprises two portions. A first portion, wherein the sampled data processed from the input signals is stored along with data processing requirements, and a second portion, wherein systems operational programmes are stored to control the processor's operation. The first portion of the memory 5 is itself divided up into 9 main storage areas each corresponding to one of the nine input signals respectively. These storage areas operate as ring stores whereby the latest signal data will overwrite the oldest. Within each area, sampled data is stored as it is processed and each area has the capacity to store up to 2000 samples, that is at least 4 seconds of data. Thus, during operation the last 4 seconds of data will be retained and available for analysis.

The processor 2 comprises a microprocessor circuit which controls the operation of the interface unit and provides the means whereby two-way communication from the interface unit to a computer can be controlled. This communication is preferably achieved via a serial interface 6 which provides signal levels compatible with RS 232 serial interface standards so that the interface

unit can be connected directly to a computer's serial input port. However, in order to protect the patient from any possibility of electrical shock from the computer if it is faulty, the interface unit and thereby the patient connected thereto via the electrodes is electrically isolated from the computer by means of an optical data isolation circuit 7.

Within the isolation circuit 7, a first input circuit converts the signal from electrical into optical form and these optical signals are then re-converted back into electrical form for output to the serial interface 6 by an second output circuit. Thus an isolation barrier is always maintained between the patient and the computer.

The processor side of the isolation barrier is powered by means of a power supply 8 comprising batteries. Standard Ni-Cad batteries supplying 9v are suitable for this purpose. On the computer side of the barrier, the isolation circuit is linked to the serial interface 6, which is supplied by signal lines from the computer.

Apart from the electrical isolation of the interface unit from the computer, the interface unit can also be provided with defibrillation protection if it is envisaged that the unit will be used in a situation where this may be necessary. During defibrillation, a high voltage is applied across the patient's chest and it is important to protect the unit from damage from this operation. To this end a defibrillation protection means 9 can be connected between the input buffer of the input means 1 and the electrodes connected to the patient. The protection means 9 comprises a series of electronic voltage sensitive switches which are connected to the input leads from the nine input electrodes RA, LA, LL, V1, V2, V3, V4, V5, and V6 and the common output electrode RL. A resistance in

series with the electrode connections limits the current passing down the leads and the voltage switches limit the voltage appearing at the input buffer circuit.

In use, the interface unit operates under command of its internal processor 2 to sample the signal levels of all nine input channels every 2mS and to store information relating to each signal level recorded in the memory 5. This sampling process is continuous and all input channels are sampled sequentially unless a command to cease sampling is received by the processor 2 from the computer to which the interface unit is linked.

When the interface unit is operational and linked to a computer, the unit can respond to commands from the computer to retrieve and store cardiac information from the patient, process that information and output the information to the computer for display and evaluation.

Conventionally, cardiac waveforms defined as I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, are derived from mathematical combinations of the nine input signals RA, LA, LL, V1, V2, V3, V4, V5, and V6 and the common output signal RL as follows:-

I = L-R

II = F-R

III = F-L

aVR = R-[(L+F)/2]

aVL = L-[(F+R)/2]

aVF = F-[(L+R)/2]

V1 = C1-[(L+F+R)/3]

V2 = C2-[(L+F+R)/3]

V3 = C3-[(L+F+R)/3]

V4 = C4-[(L+F+R)/3]

V5 = C5-[(L+F+R)/3]

V5 = C5-[(L+F+R)/3]V6 = C6-[(L+F+R)/3]

where R = RL input signal voltage
L = LA input signal voltage
F = LL input signal voltage
C1 = V1 input signal voltage
C2 = V2 input signal voltage
C3 = V3 input signal voltage
C4 = V4 input signal voltage
C5 = V5 input signal voltage
C6 = V6 input signal voltage

When the computer is running software for use when linked to the interface unit, the computer operator can unit to information instruct the interface send representing each of the above trace selections. On receipt of such a command, the processor 2 will formulate a trace using the appropriate formula as indicated above by manipulation of the corresponding 2mS samples to produce digital representations of the result which are then output to the computer for storage and conversion into graphical display data.

The computer can also be used to request data from any one input channel to be sent as it occurs to enable a runtime display to be produced representing cardiac activity. With a serial interface between the interface unit and the computer, and the consequent limitations of transmission speed, only one channel may be displayed at any given time. However, a parallel interface could be used, with appropriate adjustment to the software and interface unit if it were necessary in any given case to have more than one channel displayed.

Despite the foregoing, as all data from each input is stored in the memory, at the operator's request the computer can command the interface unit to cease sampling and thus retain a 4 second data block as required. Commands to the unit from the computer can now request the formulation of each or any combination of the 12 traces from the stored data by the processor 2 and these can be output to the computer for display and evaluation. This enables all twelve traces to be displayed revealing simultaneous information about cardiac activity for a continuous 4 second time period. Fig. 2 comprises a sample printout displaying such information and patient identification.

The computer can also be programmed to enlarge or reduce any screen display or printout of the traces to the operator's requirements to assist in the analysis of the information. All the displayed data can also be saved to disk in the computer for archive recording.

As previously indicated, the interface unit can also operate when it is not directly connected to a computer. In this mode, it can be used to store 4 second's worth of data in the memory 5 for later downloading to a computer for analysis. This downloading can be done in any conventional way, that is either directly or via a modem link, for example. Thus, a patient himself or general practitioner could use the interface unit to capture information for later analysis by a specialist. This should make it possible for patients to record information relating to cardiac activity of interest to a cardiologist which only occurs intermittently. A patient may therefore be saved unnecessary trips to and stays in hospital by the collection of data in this way.

It will be appreciated that compared with the cost of a conventional dedicated electrocardiagraph, the cost of manufacturing the interface unit of the present invention is inexpensive. Thus the invention provides the means whereby an electrocardiagraph can be made available cheaply to patients and doctors requiring such equipment, the doctors in particular often having a computer but are unable justify the cost of electrocardiagraph. In addition, it also has the advantage of being easily portable so that it could be carried, for example, in ambulances for use by paramedics. In such circumstances, the unit could be connected via a radio link to a remote computer located, for example at a hospital, so that a decision can be made whether to admit the patient or not without him having to be moved.

CLAIMS

- interface unit for an electrocardiagraph 1. Αn comprising data input means for connection to electrodes for attachment to a patient, data output means whereby the unit can be connected to an input of a computer to provide two-way communication between the interface and the computer, a memory capable of storing signal information from the data input means, and a processor which controls operation of the memory and which is connected to the data output means so that it can output data to the computer as requested via signals received from the computer.
- 2. A unit as claimed in Claim 1, wherein switch means are provided connected to the input means and controlled by the processor so that signal information relating to one of a plurality of input signals can be processed at any given time.
- 3. A unit as claimed in Claim 1 or Claim 2, wherein the data input means comprises nine input channels for signals from nine input electrodes and one output reference electrode.
- 4. A unit as claimed in any one of Claims 1 to 3, wherein the processor can receive signal information from all the input channels at least once every 2 mS.
- 5. A unit as claimed in any one of Claims 1 to 4, wherein the memory can store at least 2000 samples of the signal information from each input channel.

- 6. A unit as claimed in any one of Claims 1 to 5, wherein an analogue to digital converter is provided to convert each sample of the signal information from each of the input channels into an eight bit value for storage in the memory.
- 7. A unit as claimed in any one of Claims 1 to 6, wherein the data output means comprises an isolation barrier to isolate the interface unit and thereby the patient electrically from the computer when the interface unit is connected thereto.
- 8. A unit as claimed in any one of Claims 1 to 7, wherein the data input means comprises defibrillation protection means to protect the interface unit electrically from a defibrillation voltage administered to the patient.
- 9. A unit as claimed in Claim 8, wherein the defibrillation protection means comprises at least one voltage sensitive switch.
- 10. A unit as claimed in any one of Claims 1 to 9, wherein the data output means comprises a serial interface to enable signal information to be transmitted to and from the computer via a serial data input port of the computer.
- 11. An electrocardiagraph comprising a computer; electrodes for attachment to a patient; and an interface unit comprising data input means connected to the electrodes, data output means connected to an input port of the computer to provide two-way communication between the interface and the computer, a memory capable of storing signal information from the data input means, and a processor which controls operation of the memory and

which is connected to the data output means so that it can output data to the computer as requested via signals received from the computer.

12. An interface unit for an electrocardiagraph substantially as described herein with reference to Fig. 1 of the accompanying drawings.

Amendments to the claims have been filed as follows:

CLAIMS

1. An interface unit for an electrocardiograph comprising data input means comprising a plurality of input channels for signals from electrodes for attachment to a patient;

data output means whereby the unit can be connected to an input of a computer to provide two-way communication between the interface and the computer;

a power supply means independent of a power supply means for the computer;

a memory capable of storing signal information from the data input means, and

a processor connected to the data output means and which can receive signal information from all the input channels at least once every 2 mS and which controls operation of the memory so that when the interface is connected to the computer it can output data to the computer as requested via signals received from the computer.

- 2. A unit as claimed in Claim 1, wherein switch means are provided connected to the input means and controlled by the processor so that signal information relating to one of a plurality of input signals can be processed at any given time.
- 3. A unit as claimed in Claim 1 or Claim 2, wherein the data input means comprises nine input channels for signals from nine input electrodes and one output reference electrode.

į

4. A unit as claimed in any one of Claims 1 to 3, wherein the memory can store at least 2000 samples of the signal information from each input channel.

- 5. A unit as claimed in any one of Claims 1 to 4, wherein an analogue to digital converter is provided to convert each sample of the signal information from each of the input channels into an eight bit value for storage in the memory.
- 6. A unit as claimed in any one of Claims 1 to 5, wherein the data output means comprises an isolation barrier to isolate the interface unit and thereby the patient electrically from the computer when the interface unit is connected thereto.
- 7. A unit as claimed in any one of Claims 1 to 6, wherein the data input means comprises defibrillation protection means to protect the interface unit electrically from a defibrillation voltage administered to the patient.
- 8. A unit as claimed in Claim 7, wherein the defibrillation protection means comprises at least one voltage sensitive switch.
- 9. A unit as claimed in any one of Claims 1 to 8, wherein the data output means comprises a serial interface to enable signal information to be transmitted to and from the computer via a serial data input port of the computer.
- 10. An electrocardiograph comprising
 a computer;
 electrodes for attachment to a patient; and
 an interface unit comprising

data input means connected to the electrodes and comprising a plurality of input channels for signals from the electrodes;

data output means connected to an input port of the computer to provide two-way communication between the interface and the computer;

- a power supply means for the interface unit independent of a power supply means for the computer;
- a memory capable of storing signal information from the data input means, and
- a processor connected to the data output means and which can receive signal information from all the input channels at least once every 2 mS and which controls operation of the memory so that it can output data to the computer as requested via signals received from the computer.
- 11. An interface unit for an electrocardiograph substantially as described herein with reference to Fig. 1 of the accompanying drawings.

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

BLACK BORDERS

IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

FADED TEXT OR DRAWING

BLURRED OR ILLEGIBLE TEXT OR DRAWING

SKEWED/SLANTED IMAGES

COLOR OR BLACK AND WHITE PHOTOGRAPHS

GRAY SCALE DOCUMENTS

LINES OR MARKS ON ORIGINAL DOCUMENT

REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

IMAGES ARE BEST AVAILABLE COPY.

☐ OTHER: _____

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.